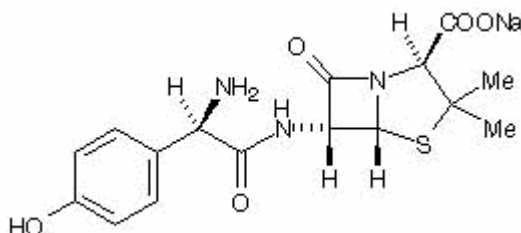


PRODUCT INFORMATION

AMOXIL[®] PARENTERAL

NAME OF THE MEDICINE

Amoxycillin sodium is a semisynthetic antibiotic and is a member of the penicillinase-stable group of penicillins derived from the penicillin nucleus, 6-aminopenicillanic acid, isolated at Beecham Research Laboratories. It is identified chemically as sodium (2S,5R,6R)-6-[[[(2R)-2-amino-2-(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate. The molecular weight of amoxycillin sodium is 387.4. Amoxycillin sodium may be represented structurally as:



CAS – 61336-70-7.

DESCRIPTION

Amoxycillin sodium is a white or almost white powder, very hygroscopic, very soluble in water, sparingly soluble in ethanol, very slightly soluble in acetone.

MICROBIOLOGY

Amoxycillin is similar to ampicillin in its bactericidal action against Gram-positive and Gram-negative susceptible organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of the cell wall mucopeptide.

It is active *in vitro* against most strains of *Haemophilus influenzae**, *Neisseria gonorrhoeae**, *Neisseria meningitidis*, *Escherichia coli**, *Proteus mirabilis** and *Salmonellae*. Because amoxycillin does not resist destruction by penicillinase, it is not active against penicillinase-producing organisms, particularly penicillinase-producing staphylococci. All strains of *Pseudomonas species*, *Klebsiella species*, *Enterobacter species*, indole-positive *Proteus species*, *Serratia marcescens*, *Citrobacter species*, penicillinase-producing *N. gonorrhoeae* and penicillinase-producing *H. influenzae* are resistant. *In vitro* studies have demonstrated the susceptibility of most strains of the following gram-positive bacteria: alpha- and beta-haemolytic streptococci, *Diplococcus pneumoniae*, non-penicillinase producing staphylococci and *Streptococcus faecalis*. These organisms are susceptible to amoxycillin at serum concentrations, which may be expected

following the recommended doses. However, some of the organisms were susceptible to amoxicillin only at concentrations achieved in the urine. (see Indications)

*Activity refers only to betalactamase negative strains.

Escherichia coli isolates are becoming increasingly resistant to amoxicillin *in vitro* due to the presence of penicillinase-producing strains.

Strains of gonococci which are relatively resistant to benzylpenicillin may be sensitive to amoxicillin.

The following *in vitro* data are available, but their clinical significance is unknown.

In vitro data for amoxicillin vs. clinical pathogens

Organism (n)	MIC90 (mcg/mL)
<i>S. pneumoniae</i> (3493) ¹	2
<i>H. influenzae</i> (3366) ¹	32
<i>S. pyogenes</i> (683) ¹	0.03
<i>H. influenzae</i> b-lac + (725) ¹	32
<i>H. influenzae</i> b-lac – (2587) ¹	1
<i>Klebsiella pneumoniae</i> (1161) ¹	32
<i>M. catarrhalis</i> (864) ¹	16
MSSA (1232) ¹	32
<i>Bacteroides fragilis</i> group (80) ²	64
<i>Fusobacterium</i> sp (23) ²	8
<i>Clostridium difficile</i> (21) ²	2
<i>N. gonorrhoeae</i> (34) ³	128

¹ Data from the Augmentin Global Surveillance Study: June 1999- December 2000 from USA, Canada, Brazil, Mexico, Hong Kong, Australia, France, Belgium, Italy, Netherlands, Spain, Sweden and the UK.

² Data from 1994-1995, France (Dubreuil L et al, 1996. In vitro evaluation of nitazoxanide and tizoxanide against anaerobes and aerobic organisms. *Antimicrob Agents Chemother.* 40(10), 2266-2270.)

³ Data from 1994-1995, UK (Wise R et al, 1996. In vitro activity of the tricyclic β -lactam GV104326. *Antimicrob Agents Chemother.* 40(5), 1248-1253.)

A positive β -lactamase test predicts resistance to penicillin, ampicillin and amoxicillin.

Rates of resistance to amoxicillin for common pathogens in Australia

Organism	Average % resistance
<i>B. fragilis</i>	100
Enterobacter spp.	96
Klebsiella spp.	98
<i>M. catarrhalis</i>	94
<i>P. aeruginosa</i>	100
<i>S. aureus</i> (methicillin-susceptible)	85
<i>Enterococcus faecalis</i>	0.2
<i>Enterococcus faecium</i>	80
<i>E. coli</i>	45.4
<i>H. influenzae</i>	20.3
<i>P. mirabilis</i>	14
<i>S. pneumoniae</i>	0.6 (fully resistant) 3.2 (intermediate resistance)

Breakpoints

Streptococcus pneumoniae: S \leq 2 mcg/ml; I = 4 mcg/ml; R \geq 8 mcg/ml

Note: Because amoxycillin has greater *in vitro* activity against *S. pneumoniae* than does ampicillin, the majority of *S. pneumoniae* strains with intermediate susceptibility to ampicillin are fully susceptible to amoxycillin.

Susceptibility Tests

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (eg. NCCLS). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.

A report of “Susceptible” indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable. A report of “Intermediate” indicates that the result should be considered equivocal, and if the microorganism is not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also provides a buffer zone, which prevents small uncontrolled technical factors from causing major discrepancies in

interpretation. A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable; other therapy should be selected.

Note: The prevalence of resistance may vary geographically for selected species and local information on resistance is desirable, particularly when treating severe infections. This information gives only an approximate guidance on probabilities whether organisms will be susceptible to amoxicillin.

Cross-resistance: Other β -lactams, β -lactam/ β -lactamase inhibitor combinations and cephalosporins

Resistance mechanisms: Production of penicillinase, altered penicillin binding proteins.

PHARMACOKINETICS

Absorption and blood levels. Following intramuscular injection of 250 or 500mg of amoxicillin, peak serum levels of approximately 5.5 microgram/mL or 10 microgram/mL are achieved within 60 minutes of injection and correspond to the peak values obtained after the same dose given orally.

Absorption from the intramuscular site is almost complete.

Following IV injection, over a 3-4 minute period, serum levels at 1 hour were similar to those seen at 1 hour after the same dose given intramuscularly. Serum levels, immediately after the IV injection were, however higher. The serum half-life measured as unchanged (active) antibiotic in the excretory phase, is approximately 1 hour in the presence of normal renal function, rising to about 7 hours with a creatinine clearance of 13 mL/minute without dialysis. The elimination half life does not appear to change until creatinine clearance reaches approximately 30 mL/minute. In patients with a creatinine clearance of 10mL/minute, elimination half life has been shown to vary between 7.5 and 21 hours after a 2g intravenous dose.

Distribution. In keeping with other penicillins, penetration into the CSF is poor in the absence of inflammation. Some penetration occurs through inflamed meninges but maximum CSF levels are very much lower than peak serum levels.

Bile levels vary with the functional integrity of secretory mechanisms, being absent in the presence of biliary tract obstruction.

Protein binding. Amoxicillin is not highly bound to human serum protein. The degree of binding as measured by ultrafiltration or equilibrium dialysis is 17%.

Excretion. The major route of excretion is renal (by glomerular filtration and tubular secretory mechanisms). The secretory mechanisms may be inhibited by the concurrent administration of probenecid, leading to prolonged and some elevation of serum levels.

Approximately 70% of a dose administered by intramuscular or rapid intravenous injection will be excreted unchanged by this mechanism in the presence of normal renal function over a six hour period, and approximately 20% will be excreted as the penicilloic acid derivative in the same time. In patients with renal failure, renal excretion falls in relation to the GFR but therapeutic levels are still maintained in the urine.

Results of studies in man, employing thin layer chromatography and bioautography, show that amoxycillin is not changed *in vivo* into substances with antibacterial activity.

There appears to be only one metabolic breakdown product, namely, penicilloic acid.

INDICATIONS

AMOXIL PARENTERAL is intended for use where the patient's condition precludes the administration of the oral form. It is indicated for the treatment of the following infections due to susceptible strains of sensitive organisms:

Note: Therapy should be guided by bacteriological studies, including sensitivity tests, and clinical response. However, in emergency cases where the causative organism has not been identified, therapy with amoxycillin may be useful. Clinical judgement will decide whether combination with another antibiotic would provide a sufficiently broad spectrum of activity pending sensitivity test results.

Septicaemia: (bacterial) *H. influenzae*; *E. coli* (see Microbiology); *P. mirabilis*; streptococcus; *S. pneumoniae*; *S. faecalis* and *Salmonella typhi*.

Skin and Skin Structure: staphylococcus, non-penicillinase-producing; streptococcus; *E. Coli* (see Microbiology).

Respiratory, Acute and Chronic: *Haemophilus influenzae*; streptococcus; *S. pneumoniae*; staphylococcus, non-penicillinase producing; *E. coli* (see Microbiology).

Genitourinary Tract (complicated and uncomplicated), Acute and Chronic: *E. coli* (see Microbiology); *P. mirabilis* and *S. faecalis*.

Gonorrhoea: *N. gonorrhoea* (non-penicillinase producing)

Prophylaxis of endocarditis: Amoxicillin may be used for the prophylaxis of bacterial endocarditis in individuals at particular risk, such as those with prosthetic heart valves or those who have previously had endocarditis.

CONTRAINDICATIONS

Amoxicillin is a penicillin and should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (eg. penicillins, cephalosporins).

PRECAUTIONS

Serious, and occasionally fatal, hypersensitivity (anaphylaxis) reactions have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral therapy. Before commencing therapy with any penicillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, appropriate therapy should be instituted and amoxicillin therapy discontinued.

Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management, including intubation, should also be administered as indicated.

Antibiotic associated pseudomembranous colitis has been reported with many antibiotics including amoxicillin. A toxin produced with *Clostridium difficile* appears to be the primary cause. The severity of the colitis may range from mild to life threatening. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However in moderate to severe cases appropriate therapy with a suitable oral antibiotic agent effective against *Clostridium difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated. Drugs which delay peristalsis, eg. opiates and diphenoxylate with atropine (Lomotil) may prolong and/or worsen the condition and should not be used.

Abnormal prolongation of prothrombin time (increased INR) has been reported rarely in patients receiving amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.

Amoxycillin has been found to cause dose related renal toxicity in laboratory animals when administered daily as a bolus injection at dose levels of 100mg/kg/day and above. As the metabolic pattern of amoxycillin in man appears to be similar to that in animals, the possibility of a nephrotoxic effect from parenteral amoxycillin should be borne in mind.

Use in pregnancy: (Category A) Animal studies with amoxycillin have shown no teratogenic effects. The product has been in extensive clinical use since 1972 and its suitability in human pregnancy has been well documented in clinical studies. Amoxycillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Use in Labour and Delivery: Oral ampicillin class antibiotics are generally poorly absorbed during labour. Studies in guinea pigs have shown that intravenous administration of ampicillin decreased the uterine tone, frequency of contractions, height of contractions and duration of contractions. However, it is not known whether the use of amoxycillin in humans during labour or delivery has immediate or delayed adverse effects on the foetus, prolongs the duration of labour or increases the likelihood that forceps delivery or other obstetrical intervention or resuscitation of the newborn will be necessary.

Use in Lactation: Ampicillin class antibiotics are excreted in the milk; therefore, caution should be exercised when amoxycillin is administered to a nursing woman.

As with any potent drug, periodic assessment of renal, hepatic and haematopoietic function should be made during prolonged therapy. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving *Aerobacter*, *Pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

The possibility of venous irritation when using that route, must be kept in mind.

Amoxycillin, an aminopenicillin, is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause is infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxycillin is used.

Amoxycillin should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to ampicillin-induced skin rashes.

During treatment with high doses of amoxycillin, particularly by bolus injection, an adequate urinary output must be maintained. Also indwelling catheters should be checked regularly for patency since, due to high urinary concentrations, amoxycillin may, at room temperature, precipitate out of solution.

Dosage should be adjusted in patients with renal impairment (see Dosage and Administration).

Lignocaine or benzyl alcohol may be used only when administering amoxicillin by the intramuscular route.

The sodium content must be taken into account in patients on a sodium restricted diet if the parenteral administration of high doses is necessary. Each 1g vial of amoxicillin contains 3.3 mmol of sodium.

Drug/Laboratory Test Interactions: Administration of Amoxicillin will result in high urine concentrations of amoxicillin. Since high urine concentrations of ampicillin may result in false positive reactions when testing for the presence of glucose in urine using Clinitest, Benedict's Solution or Fehling's Solution, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as Clinistix, or Testape) be used.

Following administration of ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated oestriol, oestriol-glucuronide, conjugated oestrone and oestradiol has been noted. This effect may also occur with amoxicillin.

Drug Interactions: Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with Amoxicillin may result in increased and prolonged blood levels of amoxicillin.

The concurrent administration of allopurinol and ampicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricemia present in these patients. Similar reactions can be expected with amoxicillin.

In common with other antibiotics, amoxicillin may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

In the literature there are rare cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin.

Tetracyclines and other bacteriostatic drugs may interfere with the bactericidal effects of amoxicillin.

ADVERSE EFFECTS

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins.

The following adverse reactions have been reported as associated with the use of Amoxicillin:

Gastro-intestinal Nausea, vomiting, diarrhoea. Intestinal candidiasis and antibiotic associated colitis (including pseudomembranous colitis and haemorrhagic colitis) have been reported rarely. (see Warnings).

Hypersensitivity reactions Erythematous maculopapular rash, pruritus and urticaria have been reported occasionally. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome, toxic epidermal necrolysis and bullous, exfoliative dermatitis and acute generalised exanthematous pustulosis (AGEP) have been reported. As with other antibiotics, severe allergic reactions including angioneurotic oedema, anaphylaxis, serum sickness, hypersensitivity vasculitis and interstitial nephritis have been reported rarely.

Whenever such reactions occur, amoxicillin should be discontinued. (Note: Urticaria, other skin rashes and serum sickness-like reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids.) Anaphylaxis is the most serious reaction experienced (see Warnings).

Liver A moderate rise in AST and/or ALT has occasionally been noted, but the significance of this finding is unknown. As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

Haemic and Lymphatic systems Reactions such as anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia and leucopenia (including severe neutropenia or agranulocytosis) have been reported during therapy with other penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena. Prolongation of bleeding time and prothrombin time have also been reported rarely.

CNS effects: CNS effects have been seen rarely. They include hyperkinesia, dizziness and convulsions. Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Injection site. Pain may be experienced at the site of intramuscular injection and phlebitis at the site of IV injection.

DOSAGE AND ADMINISTRATION

Normal Renal Function

Upper respiratory tract infections; genito-urinary tract infections; skin and soft tissue infections.

Adults - 250mg every six to eight hours, depending on the patient's condition.

Children (under 20 kg) - 20mg/kg/day in equally divided doses every six to eight hours.

In severe infections, or those caused by less susceptible organisms, 500mg every six to eight hours for adults and 40mg/kg/day in equally divided doses every six to eight hours for children may be needed.

Lower respiratory tract infections.

Adults - 500mg every six to eight hours.

Children (under 20 kg) - 40mg/kg/day in equally divided doses every six to eight hours.

Bacterial septicaemia.

In more serious infections in adults, AMOXIL PARENTERAL can be given as 1 g every six hours, slow IV injection (taking 3 to 4 minutes if injecting directly or into drip tube) or IV infusion over a period of 0.5 to 1 hour.

Children (under 20 kg) - 20-40mg/kg every 6 hours

Prophylaxis of endocarditis:

See Table.

Altered Renal Function

In renal impairment the excretion of the antibiotic will be delayed, and depending on the degree of impairment, it may be necessary to reduce the total daily dosage (see table below).

Infections complicated by renal insufficiency:

Creatinine clearance ml/min

Over 30

10 - 30

Dosage recommendations, for IV administration only in adults:

No adjustment required.

1 gram initially, then 0.5 to 1 gram every 12 to 24hrs

Less than 10	1 gram initially, then 0.5 to 1 gram every 24hrs. For <i>E.coli</i> & <i>S.faecalis</i> 1 gram every 12hrs.
Patients on haemodialysis	1 gram at the end of dialysis, then 0.5 to 1 gram every 12 to 24hrs depending on the susceptibility of the organism involved.

Note The children's dosage is intended for individuals whose weight will not cause dosage to be calculated greater than that recommended for adults. Children weighing more than 20 kg should be dosed according to the adult recommendations.

It should be recognised that in the treatment of chronic urinary tract infections, frequent bacteriological and clinical appraisals are necessary. Smaller doses than those recommended above should not be used. In stubborn infections, therapy may be required for several weeks. It may be necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

It is recommended that there be at least ten days treatment for any infection caused by haemolytic streptococci to prevent the occurrence of acute rheumatic fever or glomerulonephritis.

Directions for use:

Amoxil should be administered immediately after reconstitution to reduce the microbiological hazard. This product is intended for one patient only. Discard any remaining contents.

For direct intravenous injection, administer by slow injection (at least over a period of 3-4 minutes, preferably 10-15 minutes). More rapid administration may result in convulsive seizures.

Amoxycillin sodium is unstable in concentrated solutions and when prepared for injection, should be administered immediately.

Ig vial - For intramuscular use, add 5.2ml Water for Injections B.P. and shake vigorously. Doses larger than 500mg should be divided between multiple injection sites. Alternatively, if pain is experienced on intramuscular injection, dissolve contents in 3ml of 1% sterile lignocaine hydrochloride solution and shake vigorously. For intravenous use, dissolve contents in 20mL Water for Injections B.P. Dilutions in excess of 10mL should be carried out in the syringe.

Amoxycillin is normally reconstituted with Water for Injections B.P., however, if pain is experienced on intramuscular injection, a 0.5% solution of procaine hydrochloride or a 1% solution of lignocaine hydrochloride may be used in place of Water for Injections B.P.

A transient pink colouration may or may not develop during reconstitution. A slight opalescence may appear during reconstitution. Reconstituted solutions are normally colourless. All solutions should be shaken vigorously before injection.

OVERDOSAGE

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and symptoms of water/electrolyte imbalance should be treated symptomatically. During the administration of high doses of amoxycillin, adequate fluid intake and urinary output must be maintained to minimize the possibility of amoxycillin crystalluria.

Amoxycillin can be removed from the circulation by haemodialysis.

Contact the Poisons Information Centre (telephone 13 11 26) for advice on overdose management.

PRESENTATION AND STORAGE CONDITIONS

Stability of dry powder - Store below 25°C. Potency is maintained for 2 years.

Stability of solution - When prepared for intramuscular or direct intravenous injection, Amoxycillin should be administered immediately after reconstitution.

Stability with intravenous fluids - Infusions should be administered over a period of 0.5 to 1 hour although amoxycillin maintains a satisfactory degree of activity at room temperature in various infusion fluids.

Stability studies on amoxycillin sodium in various intravenous solutions indicate that the amoxycillin sodium will lose less than 10% activity at room temperature (20°C) for the time periods and concentrations stated in Table I.

Table 1

Intravenous solution	Concentration	Stability period
Water for injections	up to 30mg/mL	8 hours
Isotonic sodium chloride solution	up to 30mg/mL	8 hours
M/6 sodium lactate solution	up to 30mg/mL	8 hours
5% glucose in water	up to 20mg/mL	3 hours
5% glucose in water	20 to 30mg/mL	2 hours
5% glucose in 0.45% sodium chloride	up to 2mg/mL	4 hours

solution		
10% invert syrup in water	up to 2mg/mL	4 hours
Lactated Ringer's solution	up to 30mg/mL	8 hours
5% glucose, 5% ethanol in water	up to 10mg/mL	4 hours
5% glucose, 5% ethanol in water	10 to 30mg/mL	2 hours

If the solutions listed below are stored under refrigeration (4°C), they will remain stable for the time periods indicated in Table 2.

Table 2

Intravenous solution	Concentration	Stability period
Water for injections	30mg/mL	24 hours
Water for injections	up to 20mg/mL	48 hours
Isotonic sodium chloride solution	30mg/mL	8 hours
Isotonic sodium chloride solution	up to 10mg/mL	72 hours
Lactated Ringer's solution	up to 20mg/mL	24 hours
M/6 sodium lactate solution	up to 30mg/mL	8 hours
5% glucose in water	up to 20mg/mL	4 hours
5% glucose in 0.45% sodium chloride solution	up to 30mg/mL	4 hours
10% invert syrup in water	up to 30mg/mL	2 hours
5% glucose, 5% ethanol in water	up to 20mg/mL	8 hours
5% glucose, 5% ethanol in water	20 to 30mg/mL	4 hours

Since amoxicillin is relatively less stable in carbohydrate solutions, it is preferable to avoid adding it to them. It may, however, be injected into the drip tubing of such an infusion or incorporated into a small volume of the solution and infused over a period of 0.5 to 1 hour. As there is some loss of potency during storage at 4°C, solutions that have been stored at 4°C for periods within the limits stated above, should be used immediately they have been brought to room temperature.

Compatibility:

Amoxicillin is compatible with commonly used intravenous solutions as described under Stability and Storage. It should not, however, be mixed with blood products or proteinaceous fluids such as protein hydrolysates, nor with intravenous lipid emulsions.

Vials containing amoxicillin sodium equivalent to 1g of amoxicillin in boxes of 10 vials.

NAME AND ADDRESS OF THE SPONSOR

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 Australia

Telephone: (03) 9721 6000

POISON SCHEDULE OF THE MEDICINE: S4

Date of TGA Approval: 11 December 2008

Date of most recent amendment: 31 July 2009

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Version 2.0

TABLE

Based on the recommendations of the British Society for Antimicrobial Chemotherapy

Condition		Adults' Dosage (including elderly)	Children's Dosage	Notes
<p><i>Dental Procedures:</i> Prophylaxis for patients undergoing extraction, scaling or surgery involving gingival tissues, and who have not received a penicillin in the previous month. (N.B. Patients with prosthetic heart valves should be referred to hospital- see below).</p>	Patient not having general anaesthetic.	3g Amoxil orally, 1 hour before procedure. A second dose may be given 6 hours later, if considered necessary.	Under 10 years: Half adult dose. Under 5 years: Quarter adult dose.	<p><i>Note 1:</i> Prophylaxis with alternative antibiotics should be considered if the patient has received a penicillin within the previous month, or is allergic to penicillin. <i>Note 2:</i> To minimise pain on injection, Amoxil should be dissolved in sterile lignocaine 1% solution. (See Administration)</p>
	Patient having general anaesthetic: oral antibiotics not appropriate.	1g Amoxil IM immediately before induction; with 500mg orally, 6 hours later.	Under 10 years: Half adult dose.	
<p><i>Dental Procedures:</i> Patients for whom referral to hospital is recommended:</p> <p>(a) patients to be given a general anaesthetic who have been given a penicillin in the previous month. (b) patients to be given a general anaesthetic who have a prosthetic heart valve. (c) patients who have had one or more attacks of endocarditis.</p>		Initially: 1g Amoxil IM with 120mg gentamicin IM, immediately prior to anaesthesia (if given) or 15 minutes prior to dental procedure. Followed by (6 hours later): 500mg Amoxil orally.	Under 10 years: The doses of Amoxil should be half the adult dose, the dose of gentamicin should be 2mg/kg.	<p>See Note 2. <i>Note 3:</i> Amoxil and gentamicin should not be mixed in the same syringe. <i>Note 4:</i> Please consult the appropriate data sheet for full prescribing information on gentamicin.</p>
<p><i>Genito-urinary Surgery or Instrumentation:</i> Prophylaxis for patients who have no urinary tract infection and who are to have genito-urinary surgery or instrumentation under general anaesthesia. <i>Obstetric and Gynaecological Procedures and Gastro-intestinal Procedures:</i> Routine prophylaxis is recommended only for patients with prosthetic heart valves.</p>		Initially: 1g Amoxil IM with 120mg gentamicin IM, immediately before induction. Followed by (6 hours later): 500mg Amoxil orally or IM according to clinical condition.	Under 10 years: The doses of Amoxil should be half the adult dose; the dose of gentamicin should be 2mg/kg.	See Notes 2, 3 and 4 above.
<p><i>Surgery or Instrumentation of the Upper Respiratory Tract</i></p>	Patients other than those with prosthetic heart valves.	1g Amoxil IM immediately before induction. Followed by (6 hours later): 500mg Amoxil IM.	Under 10 years: Half adult dose.	<p>See Note 2 above. <i>Note 5:</i> The second dose of Amoxil may be administered orally as Amoxil Syrup.</p>
	Patients with prosthetic heart valves.	Initially: 1g Amoxil IM with 120mg gentamicin IM, immediately before induction. Followed by (6 hours later): 500mg Amoxil IM.	Under 10 years: The dose of Amoxil should be half the adult dose; the gentamicin dose should be 2mg/kg.	See Notes 2, 3, 4 and 5 above.